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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,886	03/26/2004	Marit Nilsen-Hamilton	19000.0058/P058	7776
24998	7590	01/05/2007		
DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/809,886	Applicant(s) NILSEN-HAMILTON, MARIT	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 10/06/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 04/21/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/06/2006, claims 1-33 are pending in the application and claims 1 and 3-10 are currently under examination.

### ***Response to Declaration***

The declaration filed on 10/06/2006 under 37 CFR 1.131 is sufficient to overcome the Burke et al. (Biochemistry 2002) reference.

### ***Response to Applicant's Arguments***

#### ***Claim Rejections - 35 USC § 112***

The rejection of record of claims 1 and 3-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed 10/06/2006 have been fully considered but they are not persuasive. Applicants argue they have demonstrated actual possession of the

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claimed invention because the specification discloses a complete structure of said exemplary probe. Applicants further argue in addition to providing an exemplary structure of an allosteric probe, the specification discloses guidance on a method of developing an allosteric probe and further argue the specification provides a prophetic example that illustrates an intended use for a probe and therefore the intended use provides for guidance on the probe's design. Applicant's arguments are not convincing.

While it is true the specification discloses in Example 3, an allosteric probe comprising two cis-linked aptamers wherein the first aptamer binds to a prodrug and wherein the second aptamer targets a PSCA protein, this exemplary allosteric probe does not provide adequate written description of any probe for binding a plurality of targets wherein the probe comprises an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of a regulated aptamer to a second target. Therefore, demonstration of possession of an exemplary allosteric probe targeted to a prodrug and a PSCA protein does not provide adequate written description of a probe comprising a regulator and aptamer targeted to multiple targets with the function of enhancing binding of the aptamer to any target gene.

Further, as recited in the previous office action, the specification has failed to show, for example, any core structure or motif such that a skilled artisan would know that a particular allosteric regulator when bound to a target would have the function of increasing the binding of a regulated aptamer to a second target as required by the claims. Applicants state on page 10 of the remarks filed 10/06/2006 that the

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specification notes that when designing allosteric probes, "...it is preferable to choose aptamers with affinities of at least a log unit apart with the regulated aptamer having the lowest affinity" and one of skill in the art would recognize that the method is applicable to development of allosteric probes. The specification does not provide specific guidance that would allow the skilled artisan to recognize that Applicant was in possession of the instant invention because merely choosing aptamers with affinities at least a log apart and designing allosteric probes based on this does not provide enough guidance that the allosteric probe would provide the function now claimed; binding of the allosteric regulator to a target wherein enhancement of binding of the aptamer to a second target is effected. There is no core structure or motif provided such that a skilled artisan would know that a particular allosteric regulator when bound to any target would have the function of increasing the binding of a second linked regulated aptamer to any second target. Moreover, demonstrating an intended use of a claimed allosteric probe does not provide adequate written description of the allosteric probe with the desired function as instantly claimed.

Thus, the instantly claimed invention cannot be said to have been adequately described in a way that would convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the claimed invention because the specification, while providing general information a method of making and isolating aptamers, does not provide any other information or guidance as to what allosteric regulator when linked to a regulated aptamer would increase the binding of the

regulated aptamer to second target after binding of the allosteric regulator to a first target.

***Re: Claim Rejections - 35 USC § 102***

The rejection of record of claims 1, 3, 4 and 6-8 under 35 U.S.C. 102(b) as being anticipated by Soukup et al. (TIBTECH 1999) is maintained.

Applicant's arguments filed 10/06/2006 have been fully considered but they are not persuasive. Applicants argue Soukup et al. fails to teach or suggest that binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least a second target. Applicants argue the allosteric ribozymes taught by Soukup et al. are not designed to overcome the energy barriers to the transition between certain conformational states and further the ligand binding to the allosteric site of the allosteric ribozyme enhances or inhibits the catalytic activity. Applicant's arguments are not convincing.

While Soukup et al. teach the allosteric ribozyme has increased catalytic activity after the ligand binds to the allosteric site, this increased catalytic activity is due to the ribozyme binding to the target site and as taught by Soukup et al., the allosteric ribozyme is inactive i.e. does not bind to the target site of a nucleic acid, when the ligand is not bound the allosteric site. Soukup et al. teach that when the ligand is bound to the allosteric site, the allosteric ribozyme then can bind to the target site, i.e. has enhanced binding. As defined in the specification, "enhanced binding" refers to an increased strength in the attraction or association of one molecule to another molecule

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(see page 10). Therefore, Soukup et al. teach the allosteric ribozyme has a greater association with a target gene when a ligand is bound to an allosteric site.

Thus, Soukup et al. anticipates 1, 3, 4 and 6-8 of the instant application.

The rejection of record of claims 1, 3, 4 and 6 -7 under 35 U.S.C. 102(a) as being anticipated by Chinnapen et al. (Biochemistry 2002) is withdrawn in response to Applicant's arguments filed 10/06/2006.

The rejection of record of claims 1, 3, 4 and 6-7 under 35 U.S.C. 102(a) as being anticipated by Burke et al. (Biochemistry 2002) is withdrawn in response to the declaration filed 10/06/2006.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
Art Unit 1635

JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'J. Schultz', with a long horizontal line extending to the right.